K032612

FEB 1 9 2004

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (770) 777- 4146
4-Fax: (678) 623- 3765
5-Contact Person: Jay Mansour
6-Date summary prepared: August 21st, 2003
7-Device Trade or Proprietary Name: IR FOREHEAD THERMOMETER, HV-T36
8-Device Common or usual name: Forehead Electronic Thermometer
9-Device Classification Name: Clinical Electronic Thermometer
10-Substantial Equivalency is claimed against the following device:

- FT101 Forehead Infrared Digital Thermometer, manufactured by IDT Technology Limited and distributed in US by Oregon Scientific.
  510k # K020433

11-Description of the Device:

This device is an electronic infrared digital forehead thermometer. It scans the forehead area for temperature of the arterial blood supply under the skin. The thermometer displays the results digitally as well as by talking, between 35°C (95°F) and 42.2°C (108°F).

This device includes also display of current date and time. Range of date display falls within Gregorian calendar year 1901~2099, time display includes 12 hours shift or 24 hours shift.

HV-T36 stores up to 30 sets of measurement records. Each set has a maximum storage time of 30 days. Temperature is stored together with measuring date and time of measurement.

12-Intended use of the device:

This device is an over-the-counter, non-sterile, reusable, infrared clinical electronic thermometer intended for the intermittent measurement and assessment of the skin forehead temperature of humans of all age ranges. The measured temperature correlates to axillary temperature.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SIMILAR** to the predicate device.

FDA file reference number	510k # K020433
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Similar
Radiation safety	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2004

Oriental Inspiration Limited
C/O Mr. Jay Mansour
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharette, Georgia 30022

Re: K032612
Trade/Device Name: IR Forehead Thermometer, HV-T36
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 1, 2003
Received: December 4, 2003

Dear Mr. Mansour

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032612

Device Name: IR FOREHEAD THERMOMETER, HV-T36

Indications for Use:

This device is an over-the-counter, non-sterile, reusable, infrared clinical electronic thermometer intended for the intermittent measurement and assessment of the skin forehead temperature of humans of all ages. The measured temperature correlates to axillary temperature

✓ Over-the-Counter ____ Prescription

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032612

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)